Chao, Philip L

From: John Barnard [jwb@acsion.com]
Sent: Wednesday, August 04, 1999 6:14 PM
To: pchao@oc.fda.gov
Cc: birgit.matthieson@dfait-maeci.gc.ca
Subject: Fw: US FDA Rule Changes

Importance: High

-----Original Message-----
From: Parriag, Natasha: LSB <Parriag.Natasha@ic.gc.ca>
To: John Barnard <jwb@acsion.com>
Cc: Boreskie, Mary: LSB <Boreskie.Mary@ic.gc.ca>; Leinan, Linda: LSB <Leinan.Linda@ic.gc.ca>; Chris Saunders <saunders@acsion.com>; Permut, Marsha -TCM <IMCEAX400-C=ca+3BA=govmt+2Ecanada+3BP=gc+2Bdfait+2Emaeci+3BS=permut+3BG=marsha+3B@ic.gc.ca>
Date: Wednesday, August 04, 1999 10:36 AM
Subject: RE: US FDA Rule Changes

John,

Thank you for your response to my fax dated July 23rd, regarding US FDA rule changes pending. Since our role in the Life Sciences Branch at Industry Canada is to keep health industries companies informed of policy issues such as these, I would appreciate it if you could forward your attached message directly to the FDA official responsible for this issue:

Philip Chao
tel: 301-827-3380
fax: 301-443-6906
e-mail: pchao@oc.fda.gov

You may also wish to copy Birgit Matthieson at the Canadian Embassy in Washington, D.C. at tel: 202-682-7747, fax: 202-682-7726 and e-mail: birgit.matthieson@dfait-maeci.gc.ca

It is not too late to forward your views as the comment period is still open.

Regards,
Natasha Parriag
Tel: 613-954-3160
Fax; 613-952-4209
E-mail: parriag.natasha@ic.gc.ca

From: John Barnard
To: Natasha Parriag
Cc: Chris Saunders
Subject: US FDA Rule Changes
Date: Friday, July 30, 1999 1:55PM

Natasha:

Acsion Industries Incorporated operates a 10 MeV accelerator at Whiteshell Laboratories in Pinawa Manitoba which is sometimes used for sterilization. This facility is FDA registered.

I note that the FDA's regulatory impact analysis does not account for all the costs of establishing a US agent. Therem was no allowance made for retainers, office operating costs, incorporating costs, salaries, commissions or other costs related to establishing a US Representative. These costs will easily exceed the $100 million trigger point for all small foreign suppliers.

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not aware of any such foreign regulations. However, I foresee every foreign country implementing this requirement in response to the FDA ruling, and a resulting escalation in the costs of devices and pharmeceuticals worldwide. I would certainly expect that US firms selling into Canada be subject to the same requirements as Canadian firms accessing the US market and would be lobbying Health & Wellfare Canada to formulate the required regulations as an immediate response to the US rule change. Moreover, this will be only damaging to small and medium-sized business on both sides of the border since large US and Canadian firms already have agents or subsidiary companies to act as their agents in the foreign country.

We do no medical product sterilization work at present for the US market, although from time to time we do some development work for US device firms. Therefore, I would expect that Acsion will de-register even though we intend to establish a US office in the near future.

This represents my position on the proposed FDA ruling and the course of action I will be recommending to the Acsion Board of Directors.

I am sorry if I am two days late in commenting but the comment period was short. I hope that the request for extension of the comment period was received favourably by the FDA.

John Barnard
Director of Facilities
Acsion Industries Incorporated